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NEWSLETTER

MELIOR INSIGHTS

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Melior
CAPITAL MANAGEMENT

Introduction to Melior Capital Management

MELIOR

/me'ljor/
(from Latin)

BETTER, SOUNDER, SUPERIOR

Melior Capital Management is a Swiss domiciled company introducer and advisory firm focused exclusively on the global life science sector.

We specialise in finding funding for medtech, biotech and pharmaceutical companies by applying institutional quality service and process to raise capital.

Our investment approach is to find qualified innovative projects, with proven management teams, promising data, robust IP, strong corporate governance and a likely opportunity for significant commercial upside in a three to five-year horizon.

In the current environment, many existing companies seeking capital for medical trials have encountered a diminishing supply of funding from governments, private equity firms, investment banks and research foundations in favour of start-ups. At Melior, we combine the global reputation of our scientific, management and advisory members to select best in class investment opportunities with credible upside potential.

Our value proposition is attributable to our world class team and their proven track record in the life-science sector, plus the strong emphasis that we place upon due diligence and first-hand experience. Our goal is to offer attractive and diverse investments to both high net worth private clients and larger corporates through their professional advisers. For our business to be truly successful, we consider the needs of all parties, including our investees, investors and professional advisers at introduction and throughout the life of the investment. Our financial success depends on funds raised and the financial return of our investees as we share a common goal.

In this edition of our newsletter – the Melior Insights, we look at what makes life science so attractive to many investors yet remaining virtually unexplored by investors that did not have previous experience in life science. We continue by outlining the stories of five exceptional pharmaceuticals and medical device companies respectively. Companies that a few years ago were insignificant, but through good management, wise investment and cutting-edge R&D are set to bring billions in sales. There still are companies like these on the market today, that are now in the early stages, companies that will change paradigms in life science and we, at Melior, believe that we can identify them and it is our mission to help them become successful.

Melior does not accept enquiries from members of the general public, but we welcome enquiries from professional intermediaries.

Melior Capital Management

MELIOR CAPITAL MANAGEMENT

THE LATEST THINKING ON LIFE SCIENCE INVESTMENTS

What makes life science so attractive to many investors

The world of investment is known to be complex and diverse, with investors seeking to increase their return while taking balanced risks. It is not an easy task, especially when there are so many opportunities across different investment products, deal structures and sectors – each coming with its specific advantages and risks.

There is one sector that is often overlooked by investors with limited or no experience in this field – life science. This sector can be quite intricate and technical when trying to understand the underlying processes of economic value creation. However, current research shows that life science is a wise and very lucrative investment when executed properly. Despite this, it is not a sector as celebrated as others, even though it has massive world benefits. It improves human health and the global quality of life. It is a sector that is affecting society at large, and when invested in properly, life science can propel ground-breaking and monumental change. Life science is a sector with a multitude of opportunities, aiming to bring better, cheaper and more efficient treatments to patients with various conditions and diseases. The revolutionary shift in recent years from "one-size-fits-all" drugs and technologies to targeted therapies and care, leads to more niches and projects, resulting in personalised treatment and optimal results.

> "Valuations have not been excessive in the life science industry – this is not the tech world. Life science VCs tend to be very thoughtful and conservative in how they approach a particular investment."
>
> **Mike Pellini**
>
> *A managing partner of VC firm Section 32*

When assessing investments, investors pay special attention to the valuation – an indicator that is used to understand whether it is worth gambling on a particular asset or not. If the price is exorbitant, it is unlikely to attract interest as the potential for an upside is limited and might even be non-existent. The complexity of life science sometimes make it seem like a closed club, which may result in insufficient or just appropriate levels of funding, making life science when compared to other sectors, show far more reasonable valuations, particularly compared to sectors such as information technology, financial technology (particularly cryptocurrencies) that see crowded queues of investors.

Interest in life science goes beyond the big pharma, traditional life science companies and experienced investors, there are even companies from different business niches that are attracted to life science. Alphabet, the parent company of Google, is one of the biggest advocates for life science, with its investment firm, Google Ventures backing companies that help people personalise cancer treatments and provide people with a better understanding of their own DNA. The company also established Verily, a research organisation focused exclusively on life science, with projects in robotic surgery, bioelectronic medicines and many others. In addition, in 2013 Google founded Calico – an R&D biotech company with the goal of combating aging and associated diseases. All of this showing that an IT company that reinvented the internet, firmly believes in the power and potential of life science.

Life science private investments in 2020

A good indicator for a market sector, is the private investments made both in the early stages, through venture capital and late stage / restructuring and other deals through private equity. In contrast to public markets, in the private markets investors tend to take bigger risks and push for more value creation resulting in cutting edge innovation and revolutionary products – a practice that is true for life science. The life science private market in 2020, despite being affected by the COVID-19 pandemic, has seen good development, with 10 funds closed to date, $10.2 billion raised and 2 records set - the largest life science fund ever raised in Europe (LSP 6) and the largest life science company ever funded (Blackstone Life Sciences V).

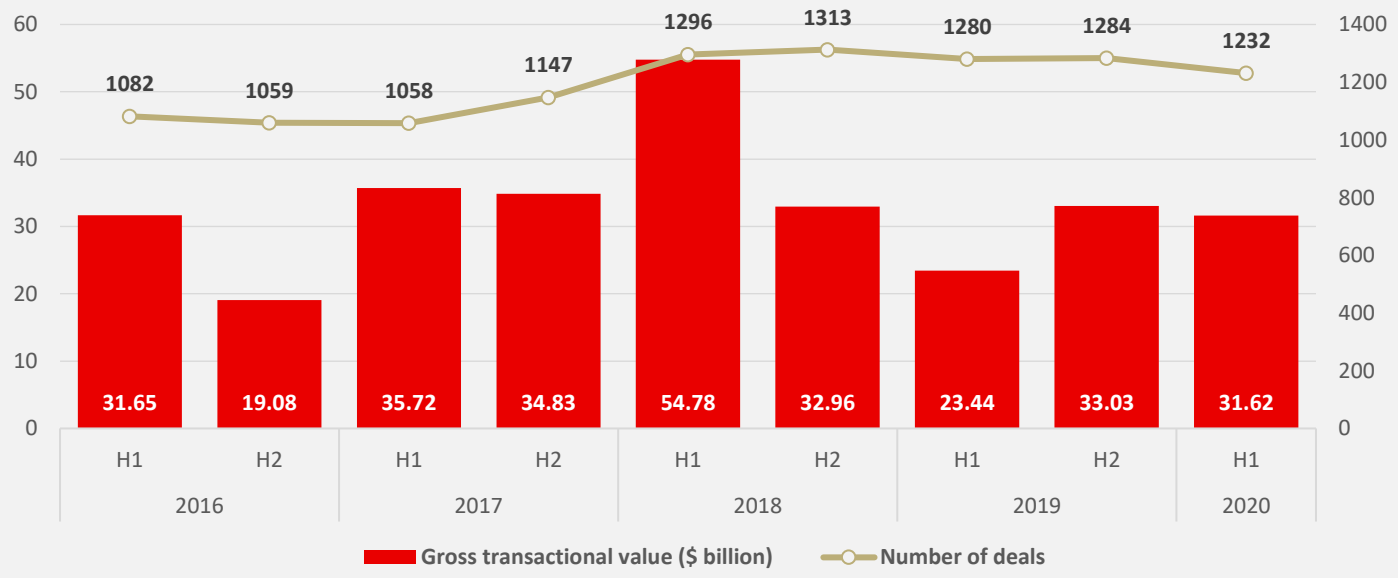
Company	Fund	Amount raised	Month	Investment focus
FRAZIER HEALTHCARE PARTNERS	Frazier Life Sciences X	$617 million	January 2020	2/3 funding into early stage and 1/3 late private and public companies
ANDREESSEN HOROWITZ	Bio Fund III	$750 million	February 2020	Early stage biology, computation and engineering
ARKIN HOLDINGS	Arkin Bio-Ventures II	$140 million	March 2020	Disruptive therapies in areas of high unmet medical need
LSP CONNECTING INVESTORS TO INVENTORS	LSP 6	$600 million	March 2020	Innovative medicines and medical device start-ups
ARCH VENTURE PARTNERS	Venture Fund X and Venture Fund X Overage	$1.46 billion	April 2020	Early-stage biotech, including COVID-19 vaccines
Flagship Pioneering	Origination Fund 7	$1.1 billion	April 2020	Innovative medicines and life science artificial intelligence
venBio	venBio Global Strategic Fund III	$394 million	April 2020	Novel therapeutics for unmet medical needs
EPIDAREX CAPITAL	Epidarex Capital III UK	$133 million	June 2020	innovative, early-stage life science companies
ATLAS VENTURE	Atlas Fund XII	$400 million	June 2020	Biotech companies targeting unmet medical needs
Blackstone	Blackstone Life Sciences V	$4.6 billion	July 2020	Strategic collaborations with established life science companies, late-stage product financing, and growth investments in emerging companies

These funds are known to be efficient in raising capital due to their long-term relationships with institutional investors and their track record, but it is often the case that they are not the most efficient players of private markets due to the large size of funds to be deployed, a temptation to rely on annual management fees rather than carried interest, and slower decision-making processes. Small and nimble investment firms tend to partner with companies capable of bringing even better returns if they use the right selection parameters.

The total of private equity /venture capital investments made in life science in the first half of 2020 reached $31.6 billion (the sum publicly disclosed – approximately one third of the 1232 transactions did not provide financial details).

Investing properly in life science:

- Proven management team
- Compelling science, not just an idea
- Advanced R&D efforts
- Existence of proper intellectual protection
- A clear path to regulatory approval
- An existing and significant market
- Possibility to scale and deploy quickly



These numbers certainly prove how compelling life science is as an investment area, although there is more potential for growth and innovation. This fact will be discussed in the following two articles of this report where five innovative drug and medical device companies are presented. Each of these companies were insignificant a few years ago but have since received remarkable valuations and are set to bring billions in sales in the next few years.

Sources: *Investing News Network, MedCityNews, TechCrunch, Blackstone, S&P Global Market Intelligence and the Melior Insights Team*

FIVE DRUGS THAT ARE SET TO BRING TENS OF BILLIONS IN SALES

The stories behind the future blockbuster drugs entering the market in 2020

The world of life science is very dynamic and every month there are many drugs and medical devices that lose their intellectual property protection, while at the same time new discoveries enter the market with the potential to revolutionise the treatment of a particular condition. Many of these discoveries bring considerable value to patients around the world and result in high sales numbers for life science companies with significant returns to investors.

GlobalData, a company specialising in data and analytics has thoroughly researched the list of drug candidates that are set to enter the market in 2020 and have identified five drugs that are forecast to have annual sales of in excess of $1 billion by 2025. Most of these drugs are innovator drugs, being the first drug of their kind. In the subsequent sub-sections, we will review where these spectacular successes originate and how they arose.

ABP 798

(Amgen and Allergan)

ABP 798 is a biosimilar of Roche's Rituxan (rituximab) and is projected to generate revenues of $4 billion by 2025. The story of ABP 798 started in December 2011, when Amgen and Watson Pharmaceuticals formed a collaboration to develop and globally commercialise four oncology antibody biosimilar medicines. In less than a year, Watson acquired Actavis for €4.25 billion and took its name. In November 2014, Actavis acquired Allergan for $70 billion and again changed its name, this time to Allergan.

In July 2015, the company sold its Generics division to Teva Pharmaceuticals for $40.5 billion and was acquired by AbbVie in June 2019 for $63 billion. In December 2019, the two companies submitted a Biologics License Application (BLA) to the US FDA for its biosimilar ABP 798. Clinical trials confirmed no clinically meaningful differences between ABP 798 and Rituxan.

This drug is set to conquer the market currently held by Roche's drug, Rituxan. ABP 798, which is sold under the brand name MabThera in Europe, and is approved to treat non-Hodgkin's Lymphoma (NHL), chronic lymphocytic leukaemia (CLL), rheumatoid arthritis (RA), granulomatosis with polyangiitis (GPA) and microscopic polyangiitis (MPA), and pemphigus vulgaris (PV). More recently in 2019, Rituxan was approved by the FDA for use in the treatment of children with NHL opening up the paediatric landscape for this biosimilar. Rituxan raised more than $9 billion in sales in 2018 boding well for ABP 798.

Ozanimod

(Bristol Myers Squibb)

Ozanimod, a new immunomodulatory oral drug, was approved by the FDA in March and is already being commercialised as Zeposia, treating relapsing forms of multiple sclerosis. Receptos, a biotech company founded in 2008, discovered the drug and conducted the first clinical trials for ozanimod in 2011. The company raised $103.5 million in two series and had its IPO on NASDAQ in May

2013 at a valuation of $257 million. Two years later, in July 2015, the company was acquired by Celgene for $7.3 billion. In February 2018, the FDA rejected the first application for ozanimod approval but even so, in January 2019, Celgene was acquired by Bristol Myers Squibb for $74 billion.

Ozanimod is expected to generate $2 billion in annual sales and is also in development for additional immune-inflammatory indications, including ulcerative colitis and Crohn's disease.

Risdiplam

(Roche)

Risdiplam, is a small molecule drug for the treatment of Spinal Muscular Atrophy (SMA), a genetic neuromuscular disorder that causes muscle weakness, affecting one in every 10,000 children born. The drug is the result of a collaboration that started in November 2011 between PTC Therapeutics and Roche. Roche paid PTC Therapeutics $30 million upfront and granted an additional $460 million in milestone payments, as well as up to double-digit royalties on commercial sales.

The drug was granted PRIME designation, which means that is a priority medicine, by the European Medicines Agency (EMA) in 2018 and Orphan Drug Designation by the US FDA in 2017. At this time, Roche has filed in Brazil, Chile, China, Indonesia, Russia, South Korea and Taiwan. The drug is currently being evaluated in four multicentre trials for people with SMA, with previous studies showing that it is efficient at treating the condition for those between 1 month and sixty years of age.

Risdiplam is set to become the third approved treatment for SMA. Roche has already stated that it plans to attempt to undercut the price of the other two competitors - Spinraza and Zolgensma, in order to gain traction with patients. The drug is expected to bring revenues of about $1.5 billion annually.

Valoctocogene roxaparvovec

(BioMarin)

Valoctocogene roxaparvovec (valrox) is a gene therapy treatment for Haemophilia. BioMarin started to develop valrox in February 2013, when it was licensed from University College London and St. Jude Children's research Hospital. In September 2015, an announcement of the first patients enrolled for the Phase 1/2 trial was made. In February 2017, PRIME status was awarded by the EMA, after receiving Orphan Drug Designation from the FDA earlier that year. In December 2017, after successful Phase 1/2 trials, the company launched a Phase 3 study. In December 2019, the EMA validated the Marketing Authorisation Application (MAA) for valrox.

In February 2020, the US FDA accepted the priority review of the Biologics License Application (BLA) for valrox for the treatment of adults with severe haemophilia A, with the final decision expected by August 21st this year. If valrox is approved, it will become the first gene therapy approved for any type of haemophilia and is anticipated to reach annual sales of $1.25 billion. To date, BioMarin has spent hundreds of millions in the research and development of this drug:

Year	Disclosed Research & Development Expenses for valrox
2016	$58.9 million
2017	$118.2 million
2018	$161.7 million
2019	$192.8 million
TOTAL	**$531.6 million**

Sacituzumab govitecan is an antibody-drug conjugate (ADC) for the treatment of breast cancer and solid tumours, which was approved by the FDA in April 2020, with the commercial name of Trodelvy.

Immunomedics began the development of their ADC program which resulted in Trodelvy back in 2012, with multicentre Phase I studies conducted in 2013, and receiving Orphan Drug designation in 2014. In February 2016, sacituzumab govitecan was granted Breakthrough Therapy designation from the FDA for the treatment of patients with Triple-negative breast cancer (TNBC) who have failed at least two prior therapies for metastatic disease. In January 2018, the company sold tiered, sales-based royalty rights on global net sales of sacituzumab govitecan for $175 million to RPI Finance Trust - funds necessary for the development of the drug's indications for urothelial cancer, metastatic breast cancer, non-small cell lung cancer and others. The company submitted the biologics license application (BLA) for sacituzumab govitecan in May 2018 and received a complete response letter (CRL), thus a refusal to approve the drug in January 2019. During 2018, Immunomedics entered into a clinical collaboration agreement with AstraZeneca, Clovis Oncology and Bayer to investigate the safety and efficacy of combined treatment with sacituzumab govitecan and their own drugs. In April 2019, Immunomedics entered into a license agreement with Everest Medicines II, granting Everest an exclusive license to develop and commercialise sacituzumab govitecan in China, Taiwan, Hong Kong, Macao, Indonesia, Philippines, Vietnam, Thailand, South Korea, Malaysia, Singapore and Mongolia, and received an upfront payment of $65 million from Everest, and milestone payments of: $60 million when FDA approval has been obtained, $180 million on achievement of certain other development targets, $530 million based on sales, as well as royalty payments ranging from 14% to 20% of net sales. In September 2019, Immunomedics entered into a clinical collaboration with GBG to develop sacituzumab govitecan as a treatment for newly diagnosed breast cancer patients. Under the terms of the agreement, GBG will arrange and sponsor the multinational Phase 3 study and is eligible to receive up to €33 million on reaching potential clinical and regulatory milestones.

The BLA was resubmitted in November 2019 and its acceptance was confirmed by the FDA in December. At the end of 2019, the company had an underwritten public offering raising $287.5 million, the primary purpose being to accelerate the commercial launch readiness of sacituzumab govitecan, as well as to expand the clinical development of this drug and the drug platform. It is forecast that sacituzumab govitecan will reach annual sales of $1 billion, while the company continues to explore its use for treating other oncology indications.

Sources: *GlobalData, BioSpace, Bristol Myers Squibb, Crunchbase, MS Discovery Forum, Roche, BioMarin, Immunomedics, and the Melior Insights Team*

FIVE MEDICAL DEVICE UPSTARTS TO WATCH

Companies that revolutionise medtech, will save lives and create investor value

The world of life science is not only comprised of exciting pharma projects – there are also cutting-edge devices. The latter usually taking less time to reach the market but being cheaper to develop. In this article, five such projects are presented as are their amazing potential to save and improve millions of patient's lives with various conditions.

ABLE Human Motion

ABLE Human Motion is a medtech start-up that commenced in 2018, aiming to develop robotic exoskeletons to improve the quality of life of individuals with Spinal Cord Injury (SCI) and related disabilities. SCI is a condition that often leaves people paralysed, resulting not only in significant stress in daily life, but also limited employment possibilities – more than 60% of people with SCI are unemployed. Currently available exoskeleton options are expensive, ranging from $67,000 to $160,000, are heavy, weighing 20 to 25 kg, leaving the wheelchair as the only viable solution. Up to 930,000 people worldwide suffer SCIs yearly. ABLE is currently conducting clinical evaluations of its product, which are scheduled to be completed soon, with the company entering into pre-sales and market approvals by the end of the year. ABLE is developing its battery-powered 8 kg exoskeleton based on extensive analysis of the human gait. The product will be connected to, and set-up via smart devices, which will enable remote monitoring by physical therapists and physicians. This technology can also be used by people with mobility problems due to stroke, polio, traumatic brain injury and multiple sclerosis, as well as by elderly people with reduced mobility who now use wheelchairs. The global robotic exoskeleton market is expected to grow at an annual increase of 45% to reach almost $ 3 billion (€ 2.7 billion) by 2023.

AbiliTech Medical

This Minnesota-based company was founded in 2016 and is focusing on developing medical devices to improve the lives of people with upper-limb impairments, including conditions like Amyotrophic Lateral Sclerosis (ALS), Brachial Plexus Injury (BPI), Muscular Dystrophy (MD), Duchenne Muscular Dystrophy (DMD), Multiple Sclerosis (MS), Spinal Cord Injuries (SCI), Spinal Muscular Atrophy (SMA) and consequences of stroke. AbiliTech is developing a range of functional assistive devices to provide support for people with the aforementioned conditions with daily activities and to allow them to achieve social, physical and economic autonomy. This year, the company is planning to launch its assistive device – a wearable device providing supported arm movement - for patients with limited strength or range of motion. In November 2019, the company raised $7.5 million to support its development. The global upper limb prosthetics market was approximated at $215 million in 2017 and is expected to reach more than $322 million in 2026.

Garwood Medical Devices

Garwood Medical Devices, is a company that was founded in 2014 with the mission of improving clinical outcomes of infections and wound healing after surgeries. BioPrax is the main product of the company – a minimally-invasive device designed to prevent biofilm infections on prosthetic knee implants by using electrodes to prevent microbial growth. In October 2019, Garwood received "Breakthrough Devices" designation from the FDA for BioPrax. The company has raised two rounds of funding, $3.6 million in September 2016 and $3.7 million in November 2019. The costs associated with the conditions targeted by this device – periprosthetic joint infections - affect tens of thousands yearly in the US alone, with one death in five people affected, resulting in billions in costs.

Parasym Health

This company, founded in 2015, develops neurostimulation products to improve the quality of life of patients with inflammatory disorders and chronic pain. The main device developed by the company, Parasym, a non-invasive neurostimulator is currently CE-marked and has been designated a non-significant risk (NSR) by the FDA. It has been given an investigational device exemption (IDE) for several research indications and may soon be available in the US outside of research settings. The global neurostimulation market, including invasive and non-invasive devices, was estimated at $5 billion in 2018, and is anticipated to grow to $12.6 billion by 2026. The Parasym device can already be purchased for GBP 599.

Signum Surgical

This Irish-based start-up, founded in 2014, is developing implants to promote healing post-surgery and to prevent infection in patients with anal fistula. Current treatments are unsatisfactory with sub-optimal patient outcomes, including infections and slow healing with patients even requiring repeated surgeries. The global market size of anal fistula was approximated at $590 million in 2017 and is estimated to reach $811 million by 2025. Signum Surgical is planning to expand into other gastrointestinal and colorectal disease conditions in the near future. The company raised EUR 2.6 million in October 2016 and EUR 3.6 million in April 2019, the last round helping the company to support a 12-month clinical study, pursue a CE mark and submit a 510(k) FDA application.

Sources: *eitHealth, Qualio, ABLE Human Motion, AbiliTech Medical, Garwood Medical Devices, Parasym, Signum Surgical, Crunchbase and the Melior Insights Team*

COMPANIONS: Pharmaceuticals and Medical Devices

Two life science components

As discussed in this report, life science is a great area for investment, creating significant value for society as a whole and yielding handsome returns for investors. The previous two articles outline a few exceptional projects in both pharmaceuticals and medical devices – two sub-sectors that drive life science development. These two sub-sectors, despite serving the same purpose – to improve health and find treatments for various conditions - are very different in many ways. In this article, the differences and similarities between these two sectors will be thoroughly reviewed.

Variety and diversity

It is estimated that more than 500,000 different types of medical devices are produced globally, compared to 20,000 medicinal products, each employed for vastly diverse health objectives. Medical devices range from simple and everyday consumer products such as spectacles, dentures and sticking plasters, to incontinence and ostomy care products, syringes and bandages, to hip implants, MRI and X-Ray equipment, and pacemakers. The technologies concerned also extend far beyond those of pharmaceutical science to include materials science, bioengineering, engineering, electronics, software, information and communication technology, nuclear, aerospace, plastics technology, surface technology and many more which are applied across all areas of clinical practice and homecare.

Research & Development

In the pre-clinical testing of medical devices, the aim is largely proof of principle, with further refinement of the product to investigate the effects the device has on a localised function, while for pharmaceuticals the process is more convoluted, as drugs may have numerous secondary effects. This causes clinical studies to start much sooner for medical devices, meaning reduced time and cost is involved in bringing medical devices to the market.

Pharmaceuticals are generally evaluated using randomised clinical trials, which is often not applicable in cases of medical devices due to ethical and practical issues in the choice of comparator – for example, what would be an ethically appropriate comparator for a cardiac pacemaker? Nonetheless, medical devices are evaluated for efficacy and safety during clinical investigations.

Regulatory

Life science is a highly regulated sector, and this remains true for its two sub-sectors. Below are the main regulatory agencies for three key regions. These institutions are the leaders of life science regulation and their practices are often followed by other regulators:

	Pharma	Medical Devices
European Union	European Medicines Agency regulates drugs	Medical devices are regulated through CE marking
United Kingdom	The Medicines and Healthcare products Regulatory Agency (MHRA) is responsible for regulating both sub-sectors	
United States	The Food and Drug Administration (FDA) regulates both sub-sectors	

Even though in the US and UK there are single agencies responsible for both sub-sectors, the regulatory process is quite different for medical devices compared to pharmaceuticals. Medical devices tend to have a much shorter product life cycle, with technical improvements of a previous iteration typically being available within two years, whereas in medicines it may take decades. Applying the same regulations would result in significant delays for medical devices and inefficiencies in treating various patient conditions with decreased safety.

Due to the complexity of pharmaceuticals and uncertainties regarding their interaction with the body, many more studies are required to ensure that there is no, or limited toxicity and side-effects.

Marketing

Medicines are most often prescribed by doctors, making them the primary target of sales and marketing activities. For medical devices, there are many more stakeholders who can influence the adoption and use of a device, including hospital managers, nurses and case workers. Medical devices therefore have greater emphasis on training, education, service and maintenance, as well as distribution, which greatly impacts their business models.

Pharmaceuticals are perceived to be more sensitive to reimbursement / insurance coverage as medical devices tend to have a longer-term usage period. Medical device companies receive less backlash from payers than drug companies typically do. For example, the $1,000 gross price per pill of the anti-Hepatitis C Virus medicine Sovaldi (sofosbuvir) was met with howls of objection from pharmacy benefit managers and US senators, while a similarly priced orthopaedic implant or pacemaker garners little reaction.

Mechanisms of action

The nature of medical devices is, as a rule, mechanical, either permanently or temporarily replacing a body function, and being relatively inert in the body. Pharmaceuticals, on the other hand, are chemical in nature and are designed to actively interact with the body's biochemistry, metabolic processes and/or immune system. Therefore, the risks to the body from pharmaceuticals are of a different order of magnitude than the risks to the body from medical devices. As indicated above, this makes the process of research and development easier for medical devices.

Efficacy dynamics

The efficacy of a medicine is simpler to demonstrate than for a medical device, because it is determined by the pharmacodynamics of its active ingredient. The effectiveness of a medical device depends upon many more variables – the individual patient characteristics, care setting, and the skills and experience of the clinician 'applying' the device. This varies per doctor, hospital and country and is thus nearly impossible to predict with any precision.

Sources: *MedTech Europe, Team Consulting, Hays, and the Melior Insights Team*

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MELIOR CAPITAL MANAGEMENT:
PIONEERING LIFE SCIENCE INVESTMENT

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